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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,698

06/02/2005

Magnus Von Knebel-Doeberitz

03528.0145.00US00

9319

27194

7590

09/22/2008

HOWREY LLP-CA

C/O IP DOCKETING DEPARTMENT

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FALLS CHURCH, VA 22042-2924

EXAMINER

AEDER, SEAN E

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

09/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,698	Applicant(s) VON KNEBEL-DOEBERITZ ET AL.	
	Examiner SEAN E. AEDER	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 30-43 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5-10,12-16,18-28 and 32-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,11,17,30 and 31 is/are rejected.
- 7) ☒ Claim(s) 4 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Election/Restriction

The Election filed 7/9/08 in response to the Office Action of 1/11/08 is acknowledged and has been entered. Applicant elected group 2 without traverse. Applicant further elects the species "TAF1B" with traverse.

The traversal is on the ground(s) that the recited species share unity of invention. Applicant cites the MPEP and states that unity of invention exists when compounds included within a Markus group (1) share a common utility, and (2) share a substantial structural feature essential to that utility. Applicant argues that the recited species share a common utility for detecting and treating disorders associated with frameshift mutations in coding microsatellites. Applicant further argues that the A11 repeats in the coding microsatellite regions of the recited species are shared substantial structural features that are essential to that utility. This is not found persuasive. While the recited species share a common asserted utility, the recited species lack a substantial structural feature essential to that utility. In regards to the argument that the A11 repeats in the coding microsatellite regions of the recited species are shared substantial structural features that are essential to that utility, the claims are not drawn to products comprising coding microsatellite regions with A11 repeats. Rather, the claimed species are drawn to polypeptides encoded by variant sequences and none of the variant sequences are required to have A11 repeats. Rather, unclaimed wild-type sequences have A11 repeats. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-28 and 30-43 are pending.

Claims 1, 2, 5-10, 12-16, 18-28, and 32-43 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claims 3, 4, 11, 17, 30, and 31 are currently under consideration.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3 and 4 are rejected under 35 U.S.C. 101 because claims 3-4, as written, do not sufficiently distinguish over polypeptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Objections

Claims 4 and 31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims

Art Unit: 1642

4 and 31 are drawn to products recited in claims from which they depend. The recited intended uses in claims 4 and 31 are not limitations.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, 11, 17, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of: (1) a genus of polypeptides encoded by a nucleic acid sequence having a frameshift mutation in TAF1B wherein the frameshift is selected from the group consisting of: (a) the insertion of one A in the A11 repeats, (b) the insertion of two A in the A11 repeats, (c) the deletion of one A in the A11 repeats, and (d) the deletion of two A in the A11 repeats; (2) a genus of polypeptides encoded by genes having a frameshift mutation in a coding microsatellite region of HT001; (3) a genus of polypeptides encoded by genes having a frameshift mutation in a coding microsatellite region of TGFB2; (4) a genus of polypeptides encoded by genes having a frameshift mutation in a coding microsatellite region of TAF1B. The specification does not disclose, and the art does not teach, the genera encompassed in the claims.

The specification states that TAF1B genes have "A11 repeats". The term "A11 repeats" is not defined by the specification or well-known in the art, but appears to refer to some sort of presence of a consecutive sequence of 11 alanine residues on the genomic coding sequence of TAF1B. However, the specification does not provide the genomic sequence of TAF1B and one of skill in the art would not know the genomic sequence of TAF1B or where "A11 repeats" are found on said sequence. Further, the specification does not disclose species representative of a genus of polypeptides encoded by a nucleic acid sequence having a frameshift mutation in TAF1B wherein the frameshift is selected from the group consisting of: (a) the insertion of one A in the A11 repeats, (b) the insertion of two A in the A11 repeats, (c) the deletion of one A in the A11 repeats, and (d) the deletion of two A in the A11 repeats. Further, the specification does not disclose species representative of polypeptides encoded by genes having frameshift mutations in coding microsatellite regions of HT001, TGFBR2, or TAF1B.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genera. That is, the specification provides neither a representative number of polypeptides that encompass the genera nor does it provide a description of structural features that are common to the genera. Since the disclosure fails to describe common attributes or characteristics that identify members of the genera, and because the genera highly variant, the disclosure is insufficient to describe the genera. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genera as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genera, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25

Art Unit: 1642

USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 4, 11, 17, 30, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al (Molecular and Cellular Biology, November 1996, 16(11):6603-6616).

Claim 3 encompasses polypeptide variants encoded by a nucleic acid sequence having a frameshift mutation in TAF1B, wherein the frameshift mutation is selected from the group consisting of: (a) the insertion of one A in the A11 repeats, (b) the insertion of two A in the A11 repeats, (c) the deletion of one A in the A11 repeats, and (d) the deletion of two A in the A11 repeats. **Note** that claim 3 encompasses any imaginable

Art Unit: 1642

polypeptide, as the gene encoding said polypeptide may have any imaginable sequence with any number of mutations in addition to a frameshift mutation selected from the group consisting of: (a) the insertion of one A in the A11 repeats, (b) the insertion of two A in the A11 repeats, (c) the deletion of one A in the A11 repeats, and (d) the deletion of two A in the A11 repeats. Claim 4 merely recites an intended use for the polypeptide of claim 3 and does not further limit claim 3. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Claim 11 is drawn to the polypeptide of claim 3 in a physiologically acceptable form. Claim 17 is drawn to a kit comprising one or more polypeptides according to claim 3. Claim 30 is drawn to a composition comprising a set of at least three frameshift polypeptides encoded by three genes having a frameshift mutation in a coding microsatellite regions, wherein the three genes are HT001, TGFB2, and TAF1B. **Note** that claim 30 encompasses any imaginable set of at least three polypeptides, as the genes encoding said polypeptides may have any imaginable sequence with any number of mutations in addition to a frameshift mutation. Claim 31 merely recites an intended use of the product of claim 30. Such an intended use is not considered a limitation.

Yang et al teaches a polypeptide, GCD2, which is encoded by a nucleic acid sequence having many mutations in addition to a frameshift mutation in TAF1B, wherein the frameshift mutation is selected from the group consisting of: (a) the insertion of one

Art Unit: 1642

A in the A11 repeats, (b) the insertion of two A in the A11 repeats, (c) the deletion of one A in the A11 repeats, and (d) the deletion of two A in the A11 repeats (see pages 604-605, in particular). Yang et al further teaches a kit comprising GCD2 in a physiologically acceptable form (left column of page 6605, in particular). Yang et al further teaches a composition comprising a set of at least three polypeptides that have many mutations including frameshifts from encoded by three genes having a frameshift mutation in a coding microsatellite regions in addition to many other mutations, wherein the three genes are HT001, TGFBR2, and TAF1B (see Figure 10, in particular).

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Examiner, Art Unit 1642